## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Ophthalmic Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee*: Ophthalmic Devices Panel of the Medical Devices Advisory Committee.

*General Function of the Committee*: To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time*: The meeting will be held on July 23, 1998, 8 a.m. to 5 p.m.

*Location*: Holiday Inn, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

*Contact Person*: Sara M. Thornton, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12396. Please call the Information Line for up-to-date information on this meeting.

*Agenda*: The committee will discuss: (1) Premarket approval application (PMA) for a toric intraocular lens for primary implantation for the visual correction of aphakia, and (2) PMA for an excimer laser for the surgical correction of hyperopia, sphere only, using photorefractive keratectomy.

*Procedure*: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by July 15, 1998. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 9 a.m. An additional 30-minute time period will be given for public comment at the end of committee discussion and prior to voting on each PMA. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 12, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 18, 1998.

**Michael A. Friedman,**

*Deputy Commissioner for Operations.*

[FR Doc. 98–17075 Filed 6–25–98; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Circulatory System Devices Panel of the Medical Devices Advisory Committee Meeting; Correction

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that published in the **Federal Register** of June 11, 1998 (63 FR 32014). The notice announced a meeting of the Circulatory System Devices Panel of the Medical Devices Advisory Committee, which is scheduled for June 29 and 30, 1998. The notice published with an error. This document corrects that error.

**FOR FURTHER INFORMATION CONTACT:** Anita Prout, Committee Management Office (HFA–306), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5503.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of June 11, 1998 (63 FR 32014), in FR Doc. 98–15602, FDA announced that a meeting of the Circulatory System Devices Panel of the Medical Devices Advisory Committee would be held on June 29 and 30, 1998. The notice incorrectly published the agenda for June 30, 1998.

Beginning on page 32014, in the 2d column, under the *Agenda* portion of the meeting, the agenda for June 30, l998, should be corrected to read: ''On June 30, 1998, the committee will discuss and make recommendations on clinical issues related to antimicrobial coatings on permanent cardiovascular implants, such as heart valves and vascular grafts.''

Dated: June 22, 1998.

**Michael A. Friedman,**

*Deputy Commissioner for Operations.*

[FR Doc. 98–17143 Filed 6–23–98; 5:02 pm]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Nonprescription Drugs Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee*: Nonprescription Drugs Advisory Committee.

*General Function of the Committee*: To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time*: The meeting will be held on July 28 and 29, 1998, 8:30 a.m. to 5 p.m.

*Location*: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

*Contact Person*: Rhonda W. Stover or Angie Whitacre, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12541. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* On July 28, 1998, the committee will discuss class labeling for over-the-counter (OTC) vaginal antifungal drug products. In the **Federal Register** of February 27, 1997 (62 FR 9024), the agency published a proposed rule intended to enable consumers to better read and understand OTC drug product labeling and to better apply this information in the labeling to the safe and effective use of such products. An important element of FDA's proposed rule is a standardized labeling format for OTC drug products. The agency has developed class labeling for OTC vaginal antifungal drug products in accordance with the February 27, 1997, proposed rule. The committee will also discuss the agency's draft guidance document for industry entitled ''Class Labeling of OTC Topical Drug Products for the Treatment of Vaginal Yeast Infections (Vulvovaginal Candidiasis)'' and other related issues. The draft guidance document is intended to provide guidance for both the carton and the educational brochure. In the next several weeks after publication of this notice, a copy of the draft guidance

document for industry will be on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday. A copy of the draft guidance document will also be available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm''.

On July 29, 1998, the committee will discuss effectiveness testing for final formulations of health-care antiseptic drug products relative to performance expectations for these OTC drug products. In the **Federal Register** of June 17, 1994 (59 FR 31402 through 31452), the agency published a proposed rule for OTC health-care antiseptic drug products, i.e., patient preoperative skin preparations, surgical hand scrubs, and health-care personnel and antiseptic handwashes. Included in the proposed rule are key characteristics for each drug product class of health-care antiseptic drug products (i.e., definitions), a requirement for final formulation testing, effectiveness standards, and labeling of each of the drug product categories. In response to the proposed rule, the agency received comments to consider six drug product categories (preoperative skin preparation, surgical hand scrub, health-care personnel handwash, food handler handwash, antimicrobial handwash, and antimicrobial bodywash). Comments also proposed alternate: (1) Testing requirements, (2) key characteristics, and (3) labeling for each of the categories. FDA is seeking the recommendations of the committee and experts on appropriate performance expectations for OTC health-care antiseptic drug products and how these final formulations should be tested.

*Procedure*: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by July 21, 1998. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on July 28 and 29, 1998. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 21, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 18, 1998.

**Michael A. Friedman,**

*Deputy Commissioner for Operations.*

[FR Doc. 98–17074 Filed 6–25–98; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

**[HCFA–R–224]**

### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Collection of Managed Care Data Using the Uniform Institutional Providers Form (HCFA–1450/UB–92) and Supporting Statute Section 1853(a)(3) of the Balanced budget Act of 1997; *Form No.:* HCFA–R–224 (OMB No. 0938–0711); *Use:* Section 1853(a)(3) of the Balanced Budget Act (BBA) requires Medicare+Choice organizations, as well as eligible organizations with risk-sharing contracts under section 1876, to submit encounter data. Data regarding inpatient hospital services are required for periods beginning on or after July 1, 1997. These data may be collected starting January 1, 1998. Other data (as the Secretary deems necessary) may be required beginning July 1, 1998.

The BBA also requires the Secretary to implement a risk adjustment methodology that accounts for variation in per capita costs based on health status. This payment method must be implemented no later than January 1, 2000. The encounter data are necessary to implement a risk adjustment methodology.

Hospital data from the period, July 1, 1997–June 30, 1998, will serve as the basis for plan-level estimates of risk adjusted payments. These estimates will be provided to plans by March, 1999. Encounter data collected from subsequent time periods will serve as the basis for actual payments to plans for CY 2000 and beyond.

In implementing the requirements of the BBA, hospitals will submit data to the managed care plan for enrollees who have a hospital discharge using the HCFA–1450 (UB–92), Uniform Institutional Provider Claim Form. Encounter data for hospital discharges occurring on or after July 1, 1997 are required. While submission from the hospital to the plan is required, plans are provided with an alternate submission route for the start-up year.

Special procedures have been identified to ensure that hospital encounter data are submitted for discharges occurring between July 1, 1997 and June 30, 1998, the start-up year. HCFA has identified three alternatives for the submission of hospital encounter data for discharges during the star-up year, including the following:

Option 1: The Plan will have a hospital submit UB–92s or Medicare Part A ANSI ASC X12 837 (ANSI 837) records using the traditional HMO ''No Pay'' bill method.

Option 2: The Plan can currently produce a complete UB–92/ANSI 837 and will hold the data until the fiscal intermediary (FI) can accept it.

Option 3: The Plan will submit an abbreviated UB–92 data set via an alternative route.

During the start up year, the plan is expected to establish an electronic data linkage to a FI to be determined by HCFA. HCFA will assist Plans in initiating discussions with their FI. By July 15, 1998, the Plan is expected to have completed this linkage, including testing of the linkage, and to be capable of transmitting hospital encounter data to a FI. Data for the start-up year must be transmitted to the plan's FI by September, 18, 1998. All data with discharge dates after July 1, 1998 will be transmitted using this linkage. (See Appendix III for additional information on the transmission of data to HCFA.) Each plan and/or contract will use a single FI. HCFA will establish a series of interim deadlines to ensure that plans are making sufficient progress toward